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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,569	10/06/2003	Carlos E. Collazo	OSTEONICS 3.0-456	3144
530	7590	03/10/2005	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			REIMERS, ANNETTE R	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,569	COLLAZO, CARLOS E.	
	Examiner	Art Unit	
	Annette R. Reimers	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
 - 4a) Of the above claim(s) 1-11, 17 and 19 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 12-16, 18 and 20-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 06 October 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/06/03</u>. | <ol style="list-style-type: none"> 4)<input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. 5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6)<input type="checkbox"/> Other: _____. |
|---|--|

DETAILED ACTION

Election/Restrictions

Applicant's election of Group III, claims 12-16 and 18 and Species III, Figures 1-5, in the reply filed on 01/03/05 is acknowledged. It is further acknowledged that applicant believes that claims 1-5 read on the elected Species. In addition, the examiner agrees with the applicant. Furthermore, claim 12 appears to be generic.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).

Claims 1-11, 17, and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was interpreted as made **without** traverse in the reply filed on 01/03/05.

Specification

The specification is objected to because reference number 36, lines 19 and 26 of page 6, has inconsistent terminology, i.e. bearing surface and undersurface, respectively. Please clarify whether reference number 36 refers to bearing surface or undersurface. In addition, reference number 45, lines 8 and 11 of page 7, has inconsistent terminology, i.e. fins and flutes, respectively. Please clarify whether reference number 45 refers to fins or flutes.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-16, 18 and 20-24 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 12, line 1, applicant positively recites part of a human, i.e. "mounted in a fixture aligned with a bone canal". Thus claims 12-16, 18 and 20-24 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which the applicant regards as the invention.

In claim 13, line 2, "said bushing central opening" lacks proper antecedent basis.

Also, in claim 13, lines 2-3, "the largest radial extent" lacks proper antecedent basis.

In claim 14, line 2, "the number of flutes" lacks proper antecedent basis.

In claim 15, line 2, "said central opening" lacks proper antecedent basis.

In claim 16, line 2, "said central shaft" lacks proper antecedent basis.

In claim 24, line 2, "said central opening" lacks proper antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12-16, 18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cenis (U.S. Patent Number 3,981,604).

Cenis discloses a cylindrical bushing, e.g. figure 2, comprising a body with a bearing surface, e.g. 21 of figures 2 and 3, extending circumferentially around an outer cylindrical surface of the bushing, a longitudinal bore formed in the body (see figure 2) and a plurality of recesses extending radially outward from the bushing central bore, e.g. 22 of figure 2. In addition, the cylindrical outer bearing surface extends about an axis, which is coaxial with an axis of the longitudinal bore (see figures 2 and 3).

Each recess is capable of receiving at least two flutes (see figures 2, 4, and 5). Furthermore, the recesses are capable of extending a distance greater than the largest radial extent of the flutes of the at least two reamers, since the Cenis bushing device

can accommodate any reamer design having straight flutes (see figures 2, 4 and 5). Moreover, the bushing is capable of having a number of recesses equal to or greater than the number of flutes of each of the reamers (see figures 2, 4, and 5). In addition, the recesses and the flutes expand in width on moving radially outward from the central opening or shaft, respectively (see figure 4).

Claims 12-14, 18 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Ball et al. (U.S. Patent Publication 2003/0163151).

Ball et al. disclose a cylindrical bushing, e.g. figure 4, comprising a body with a bearing surface, e.g. 23 of figure 4, extending circumferentially around an outer cylindrical surface of the bushing, a longitudinal bore formed in the body (see figure 4) and a plurality of recesses extending radially outward from the bushing central bore, (see figure 4). In addition, the cylindrical outer bearing surface extends about an axis, which is coaxial with an axis of the longitudinal bore (see figures 4 and 5).

Each recess is capable of receiving at least two flutes (see figure 4). Furthermore, the recesses are capable of extending a distance greater than the largest radial extent of the flutes of the at least two reamers, since the Ball bushing device can accommodate any reamer design having straight flutes (see figure 4). Moreover, the bushing is capable of having a number of recesses equal to or greater than the number of flutes of each of the reamers (see figure 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3732

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cenis (U.S. Patent Number 3,981,604).

Cenis discloses the claimed invention except for where the plurality of recesses have radial ends opposite ends thereof open to the bore at a shorter radial distance from the axis of the longitudinal bore than the outer cylindrical surface of the bushing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Cenis where the plurality of recesses have radial ends opposite ends thereof open to the bore at a shorter radial distance from the axis of the longitudinal bore than the outer cylindrical surface of the bushing, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for art cited of interest.

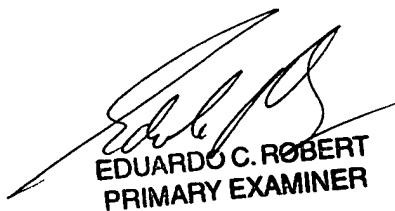
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday, 9:00AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EDUARDO C. ROBERT
PRIMARY EXAMINER